Decision Summary

The Centers for Medicare & Medicaid Services (CMS), while awaiting the publication of SCD-HeFT, will retain implantable cardioverter defibrillator (ICD) coverage for patients currently eligible and may cover ICDs for patients with characteristics of the SCD-HeFT trail under Category B IDE trials and the CMS routine costs in clinical trials policy (CIM 30-1, NCD 130.1). The ICD policy is available on our web site at http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=20.4&ncd_version=2&basket=ncd%3A20%2E4%3A2%3AImplantable+Automatic+Defibrillators.

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Decision Memo

To: Administrative File: CAG 00157R2
Implantable Defibrillators

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Subject: Coverage Decision Memorandum for Implantable Cardioverter Defibrillators
Date: December 28, 2004

I. Decision

The Centers for Medicare & Medicaid Services (CMS), while awaiting the publication of SCD-HeFT, will retain implantable cardioverter defibrillator (ICD) coverage for patients currently eligible and may cover ICDs for patients with characteristics of the SCD-HeFT trail under Category B IDE trials and the CMS routine costs in clinical trials policy (CIM 30-1, NCD 130.1). The ICD policy is available on our web site at http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=20.4&ncd_version=2&basket=ncd%3A20%2E4%3A2%3AImplantable+Automatic+Defibrillators.

II. Background

CMS initiated this national coverage decision (NCD) process with the expectation that the final decision would be posted no later than December 28, 2004, in accordance with the accelerated time frame established by Section 731 of the MMA. As has long been the standard, when the basis for an NCD is a clinical trial, CMS requires publication of the trial results in a peer-reviewed journal before those results can be used as the basis for implementing a national coverage decision. The results of the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) trial, the major source of evidence for this NCD, have not yet been published in a peer-reviewed journala critical step in validating the evidence underlying this coverage determination.

III. Timeline of Recent Activities

6/6/2003	CMS issues the decision memorandum discussing the intent to expand coverage to patients with a previous myocardial infarction, low ejection fraction and wide QRS interval. This decision is based on data from the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II).
10/1/03	Coverage in the June 2003 decision memorandum becomes effective.
3/8/04	The principal investigator of SCD-HeFT presents the primary trial results at the American College of Cardiology annual scientific session.
3/12/04	CMS issues a follow up decision memorandum to further explain the decision to allow coverage under IDE Category B clinical trials.
3/18/04	CMS meets with Medtronic Inc. to discuss results of SCD-HeFT.
3/30/04	

	CMS accepts a reconsideration request from Medtronic Inc. to expand coverage of ICDs to patients with SCD-HeFT indications. Tracking sheet is posted to our web site and the initial open public comment period begins.
4/14/04	Teleconference with the requestor.
4/22/04	CMS meets with St. Jude Medical to discuss recent clinical trials studying ICDs.
4/30/04	Initial open public comment period ends.
5/3/04	CMS meets with Guidant Corporation to discuss recent clinical trials studying ICDs.
5/17/04	Teleconference with requestor.
5/22/04	SCD-HeFT investigators present additional data from the trial at the Heart Rhythm Society’s annual scientific session.
5/25/04	

	CMS requests a second open public comment period to receive comments on the COMPANION and DEFINITE trials that were published after the close of the initial comment period.
6/7/04	Posting of comments received in the initial public comment period.
6/8/04	CMS meets with the Heart Rhythm Society and the American College of Cardiology to discuss appropriate device selection.
6/23/04	CMS requests a third open public comment period to receive comments on threshold testing, anti-tachycardia pacing (ATP), risk associated with the ATP lead and an ICD patient registry.
6/25/04	Second public comment period closes.
6/28/04	Teleconference with requestor.
7/1/04	Posting of comments received in the second public comment period.
7/23/04	Third public comment period closes.

8/9/04	Posting of comments received in the third public comment period.
10/28/04	Posting of proposed decision memorandum for 30-day public comment period.
11/28/04	Public comment closes on the proposed decision memorandum.
12/3/04	Posting of the ICD registry recommendations by the National ICD Registry Workgroup, chaired by the Heart Rhythm Society.
12/3/04	Posting of the public comments received in the 30-day public comment period for the proposed decision memorandum.
12/16/04	Posting of tracking sheet update announcing that the results of SCD-HeFT may not published in a peer-reviewed journal before the MMA established time frame and previous coverage would continue until publication.
12/23/04	CMS posts the ICD registry hypotheses and data elements.

12/28/04	Decision memorandum continuing previous ICD coverage is posted.

IV. Public Comments

Comments on Proposed ICD Decision Memorandum

In response to the reconsideration proposed decision memorandum posted on September 28, 2004, we received comments from 374 individuals and groups during the required statutory period ending October 28, 2004. Commenters included major national professional associations (e.g., electrophysiologists, cardiologists, heart failure specialists), patient advocacy groups, national associations of health plans and of device manufacturers, academic researchers, practicing professionals, and other individuals including patients and caregivers. The majority of commenters supported the expanded coverage in the proposed decision memorandum. Many commenters, however, did not agree completely with the proposed coverage and had additional concerns. A summary of the comments is provided below.

General Comments

Of the total, 261 commenters stated that CMS was improving access to ICDs by expanding coverage but the expansion did not include all patients at risk for sudden cardiac death. The commenters encouraged CMS to cover all patients at risk; however, characteristics of the population at risk were not identified.

T-Wave Alternans Testing

CMS received 29 comments regarding the use of T-wave alternans testing as a risk-stratifier for sudden cardiac death. Two commenters recommended against T-wave as a risk-stratifying mechanism. One commenter specifically stated that the technology had not undergone rigorous scrutiny, the test could not be easily applied and the results were not reproducible. Remaining commenters supported the use of T-wave alternans and about half of the supporters wanted T-wave alternans testing to be part of the ICD registry. One commenter made the suggestion to learn more about the predictive value of the test but stated that it is not yet ready for use in practice to determine ICD eligibility.

End of Life Care

Two commenters were concerned with the use of these devices in nursing home patients and patients nearing the end of life. They specifically addressed the need for physicians to discuss end of life care with patients and their families including options of not having the device implanted or turning the device "off" at a later time. One commenter requested that we collect end of life information in the ICD registry to inform us about the number of patients that choose to have their devices turned off. This is an important concern that was given careful thought in previous ICD decisions which led to noncoverage of implantations in patients with irreversible brain damage, disease, or dysfunction that precludes the ability to give informed consent or any other disease in which the likelihood of survival is less than one year.

New York Heart Association Class IV Congestive Heart Failure (CHF)

CMS received approximately 20 comments concerning the noncoverage of ICDs for Class IV CHF patients particularly in combination with cardiac resynchronization therapy (CRT) devices. Commenters recommended that CMS change the coverage decision to include this class of patient for coverage. Most suggested that these patients should be eligible to receive the combined cardiac ventricular resynchronization and defibrillator (CRT-D, also referred to as a combined biventricular pacing and defibrillator device) therapy with the potential of improving their heart failure class to III. By noncovering Class IV, commenters noted that physicians would be forced to implant a CRT device to improve the patient to Class III CHF and then implant the CRT-D therefore exposing the patients to multiple procedures. Commenters also addressed the benefits of CRT-D in Class IV CHF patients such as less hospitalizations and lower use of medications. One commenter stated that Class IV CHF patients should be covered for CRT-D only when that patient has a reasonable expectation of improving to Class III CHF.

New York Heart Association Class I CHF

One commenter recommended that CMS exclude coverage of Class I CHF patients since studies have not demonstrated a benefit in this group.

Nonischemic Dilated Cardiomyopathy (NIDCM) for 9 months

CMS received approximately 20 comments on the coverage requirement that patients have NIDCM for at least 9 months prior to ICD implantation. Slightly more than half of these commenters favored the SCD-HeFT requirements, that patients have NIDCM for 3 months prior to implantation. They believed that the overall outcome of SCD-HeFT demonstrated that these patients benefit from ICD therapy and that subgroup analysis should not be used to exclude them from coverage. Of the commenters that favored the CMS requirement of 9 months, they agreed that a 9 month interval was appropriate to exclude patients with reversible disease and allow time for evaluating the response to treatment with optimal medical therapy.

Device Selection

Approximately 40 comments were received regarding device selection with one-third of those in support of CMS issuing guidance or policy regarding appropriate use. Some commenters believed that CMS policy would reduce overuse of sophisticated devices when they are not truly indicated. The requirement of documenting the reason for device selection was favored by some. The majority of commenters strongly suggested that CMS remove the term "shock-only" from the coverage determination. "Shock-only" implied to some commenters that ATP and RV pacing were not options on a simple ICD. Commenters wanted the option of programming these functions on simple, single-chamber devices. Many commenters were concerned that inability to program ATP would result in unnecessary shocks. Other commenters were concerned that initial implantation of a simple device would later be followed by implantation of a more sophisticated device as the patient's condition worsens or the need for additional leads is indicated thus exposing the patient to multiple procedures. It was noted that SCD-HeFT was not designed to study device selection and coverage restrictions should not be developed from the results of the study.

Left Ventricular Ejection Fraction (LVEF)

CMS received approximately 40 comments regarding ejection fraction requirements. Commenters stated that CMS should change the coverage determination to include patients with ejection fractions of $\leq$ 0.35 rather than $\leq$ 0.30. It was pointed out that the population included SCD-HeFT and COMPANION and those trials showed overall benefit. Commenters strongly suggested that subgroup analyses should not be used to determine the ejection fraction limits. In addition, one-fourth of comments regarding ejection fraction recommended the use of cardiac magnetic resonance imaging to measure ejection fraction.

Myocardial Infarction (MI) < 1 month, Percutaneous Transluminal Coronary Angioplasty (PTCA) < 3 months

CMS received approximately 10 comments concerning the restriction of coverage to patients with an MI greater than 1 month prior to ICD implantation and PTCA greater than 3 months prior to implantation. Commenters stated that this requirement should not apply to patients that already met the criteria for implantation prior to their most recent event or procedure. However, most commenters agreed that patients presenting with a new MI should be required to wait 1 month.

Physician Criteria

Approximately 20 comments were received concerning physician criteria for implanting ICDs. There was a range of criteria recommendations with about half supporting that implanters must be board certified electrophysiologists and the other half supporting the recent Heart Rhythm Society guidelines for non-electrophysiologist implanters. Others noted that experienced, non-electrophysiologists that are currently implanting should be grandfathered into the requirement and one commenter noted the need to consider concerns of partially disabled physicians that implant with assistance of other physicians.

Threshold Testing

Regarding threshold testing, CMS received approximately 10 comments with each supporting the need for testing at the time of implant to ensure appropriate device programming and lead placement.

Registry

Approximately 45 comments discussed the CMS requirement that patients receiving an ICD for primary prevention of sudden cardiac death be enrolled in a registry. Many commenters supported a registry with certain conditions while others did not support a registry in any way. Commenters that did not agree with a registry requirement stated that the evidence from clinical trials already demonstrate ICD benefit for primary prevention and further study through a registry is not necessary and would add no value. Others commented that a registry would not be possible at their institutions because institutional review boards would not approve participation, they would violate privacy and confidentiality requirements of the Health Insurance Portability and Accountability Act or the burden on their resources would be too great. Many commenters raised questions about details of the registry that were not outlined in the proposed decision memorandum such as hypotheses, data elements, funding, management, analysis and access.

Some commenters were concerned that requiring a registry would delay coverage and limit patient access. Their recommendations included allowing a grace period between the effective date of coverage and registry participation, decoupling registry participation from payment and requiring a sampling of ICD patients rather than the entire Medicare primary prevention population.

Registry supporters stated that an ICD registry could provide real-world outcomes, assist in answering questions that require a large sample size such as subgroups of women and patients over age 80 and may be hypothesis generating in regard to risk stratification. Commenters made various recommendations on implementing a registry. One commenter suggested that only one registry be used to facilitate tracking and auditing rather than allowing multiple registries to collect data. Other commenters suggested that a valuable registry could be implemented if it was done carefully, with good planning, cooperation from stakeholders and had credible oversight.

CMS Response to Public Comments

Public commenters raised several important issues. Once the publication on SCD-HeFT main results is available, CMS will carefully evaluate the evidence on the various issues raised by public commenters and will provide more specific responses in the final decision.

V. Conclusion

Since a peer-reviewed article on the SCD-HeFT has not been published, CMS concludes that we do not have adequate evidence to expand coverage. Therefore, we are maintaining current ICD coverage. A peer-reviewed publication is an important element in the coverage determination process. It provides an opportunity for the public to review the trial data and to consider our interpretation of the trial results and conclusions based on the trial results. CMS will reconsider expansion of ICD coverage immediately following publication of the SCD-HeFT trial results.

While we await the publication of SCD-HeFT, patients currently eligible for ICDs retain that eligibility and coverage of an ICD for patients with characteristics of the SCD-HeFT trial population may still be available under Category B IDE trials and the CMS routine clinical trials policy (CIM 30-1, NCD 310.1).

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